K022004

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II. 510K SUMMARY

Revised: 11 December, 2002

1. Submitted by:

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2. Contact Person:

Jorge Haider

3. Device Identification:

Trade Name:	Inline Sensor Assembly and Inline Temperature Sensor
Common Name:	In-line injectate system
Classification Name:	Short-term Intravascular Catheter and Accessories

4. Predicate Device(s):

Becton Dickinson & Co. (B-D) (formerly Gould Inc. Oxnard, CA, K830523) SP4500 sterile In-line injectate system

5. Device Description:

Biosensors Cardiac Output Kit is a sterile kit of disposables which includes an in-line injectate sensor housing along with a 10 ml syringe, 3-way stopcock, a dual one-way check valve adaptor housing and a coil of IV tubing with spike and a tubing clamp. The check valve prevents reflux of fluid and/or blood into the system following injection of saline into a Thermodilution Catheter (not a part of this application).

6. Intended Use:

Biosensors Inline Sensor Assembly forms a close loop injectate system for cardiac output measurement. Inline Temperature Sensor and kits (Inline Sensor Assembly) are used in Critical Care and Surgery settings in conjunction with Thermodilution Catheters supplied by various manufacturers, including Biosensors (K911710), for measuring cardiac output of hemodynamically compromised patients by Thermodilution Technique. In this procedure, a known quantity of "room temperature" saline is injected from the Inline Sensor Assembly, and then through an internal catheter lumen to a proximal port of the catheter and into the patient's heart (right atrium). The room temperature saline mixes with the patients' blood as it is pumped by the heart through the right ventricle and into the pulmonary artery. Thermodilution catheters are equipped with a temperature sensor located at

the tip of the catheter in the Pulmonary Artery. The pulmonary artery thermistor sensor (not a part of this product) reports the transient reduction in temperature of the saline-blood admixture as it flows past the tip of the Thermodilution Catheter via a separate electrical cable hookup to the Marquette 7000 Series Patient Monitor, which is equipped with software to display the "Thermodilution curve" (i.e. time-varying temperature signal) and to compute the cardiac output (blood flow in L/min) of the patient. For the computed cardiac output measurement to be accurate, the exact temperature (+-0.3 deg C) of the 10CC of saline injected via the kit must be known to the software. The Inline Temperature Sensor mates with the Kit, to provide an accurate, fast responding measurement of the saline temperature as if flows through the kits' Injectate Sensor Housing. The Inline Temperature Sensor cable is a reusable item, the tip of which contains a linearized thermistor bead pair that is electrically and fluidically isolated from the saline inside the kit. The "temperature signal" is conveyed across a metal ferrule positioned in the center of the fluid flow path inside the sensor housing. The sensors housing is one of the components of the sterile, single-use Kit. The inside of the metal ferrule, which is in close contact with the temperature sensitive tip of the cable, thus allows the thermistor to rapidly sense and report, through an electrical resistance change, any change in the temperature of the saline as it is injected through the kit.

7. **Summary of Technological Characteristics of Device in relation to Predicate Device(s):**
   Biosensors Inline Sensor Assembly and Inline Temperature Sensor is basically the same in design safety and performance to Becton Dickinson's sterile, package, disposable SP4572 system and make of the same generic polymer types as used in the predicate devices, but the materials used are not identical to those materials used in the B-D kit.

8. **Assessment of Performance Data used to justify Substantial Equivalence Claim:**
   BSI's Inline Sensor Assembly was evaluated in accordance with ISO 10555-1, ISO 8536-4 and ANSI/AAMI ES1-1993 ISO10555. The devices were found to meet or exceed the requirements of the standards, or perform as well as, or better than predicate devices. The following characteristics were evaluated: tensile strength of tubing and bonded joints, liquid leakage under pressure, temperature accuracy and response time, injection volume and maximum current limits at single fault condition. In addition, all materials used were shown to meet biocompatibility requirements outlined in ISO 10993.

9. **Conclusion:**
   Based on the test data gathered, Biosensors Inline Sensor Assembly and Inline Temperature Sensor are substantially equivalent to the predicate Becton Dickinson's CO Set and temperature probe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Biosensors International-USA, Inc.
c/o Mr. Jorge Haider
Director, Regulatory Affairs
20250 Acacia St., Suite 115
Newport Beach, CA 92660

Re: K022004
Trade Name: Inline Sensor Assembly and Inline Temperature Sensor
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: December 11, 2002
Received: December 12, 2002

Dear Mr. Haider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022004

Device Name: Inline Sensor Assembly and Inline Temperature Sensor

Indications for Use:

Biosensors Inline Sensor Assembly is designed for closed injectate delivery system use. It connects to the CVP lumen of a Thermodilution catheter to perform room temperature injections and determine a temperature reading. The inline temperature sensor housing connects to a reusable thermistor cable assembly (the Inline Temperature Assembly) that leads to a Marquette 7000 series Cardiac Output Computer. An inline check valve prevents reflux of fluid and/or blood into the system after injections. The intended use of Biosensors Inline Sensor Assembly is identical to that of Becton Dickinson's SP4572 disposable in-line injectate set.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A NOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022004

Prescription Use ✓